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LabLink

this issue

Director of the Chemistry & Toxicology Division- Sara Tomechko, Ph.D

We're pleased to announce the appointment of Sara Tomechko, Ph.D. to Chemistry and Toxicology Division Director effective October 27, 2014.

Dr. Tomechko obtained her undergraduate degree from Kent State University. She then acquired a master's degree in Bioanalytical Chemistry from the Ohio State University and a doctorate in Analytical Chemistry from the University of Akron. While pursuing her doctorate degree, her primary research focus was polymer mass spectrometry. For her first post-doctoral fellowship, she switched fields and studied molecular cardiology at Cleveland Clinic. Dr. Tomechko spent the next five years completing another post-doctoral fellowship and serving as staff in the medical school at Case Western Reserve University. During her tenure, her research focused on protein, transcript and gene dysregulation as a function of disease or drug treatment in the areas of glioblastoma multiforme, diabetes, pelvic floor collapse, tuberculosis, and sleep apnea. She also taught graduate classes in the nursing school and in the systems biology program.

Please feel free to contact her regarding any issues related to Chemistry, Toxicology and Newborn Screening laboratory testing. She can be reached at (517)335-9490 or by email at TomechkoS@michigan.gov.

Director,
Bureau of Laboratories
Sandip Shah, Ph.D.,
HCLD(ABB)

CAP ACCREDITED

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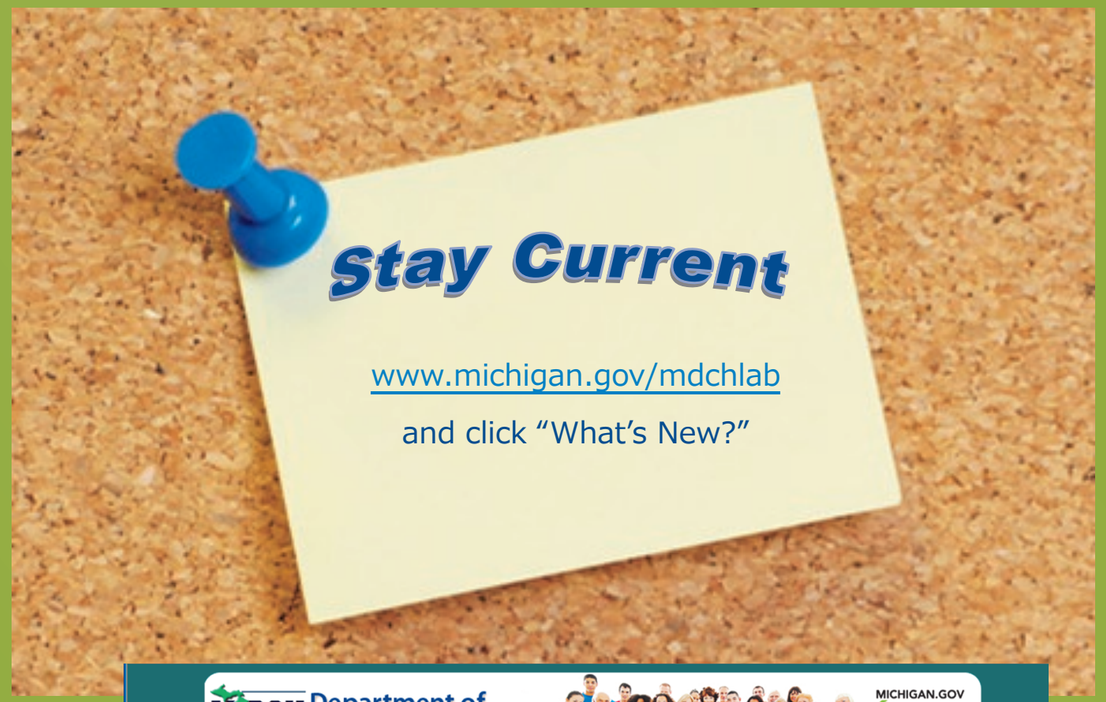


"BOL response to the BioFire EUA"

A message from Dr. Sandip Shah
State Public Health Laboratory Director

With the situation concerning Ebola, the state continues to coordinate with the health and medical community to protect residents and ensure adequate training, education and equipment for healthcare workers. As the Centers for Disease Control and Prevention (CDC) updates their standard protocols used in hospitals to maintain safe work procedures for laboratories and healthcare workers, the Michigan Department of Community Health (MDCH), Bureau of Laboratories (BOL) and Office of Public Health Preparedness (OPHP) continue to send out health alert messages and partner with hospitals, health departments, physicians, nurses, laboratory staff and other health care providers to protect against any threat the Ebola virus may pose to our state and its citizens.

The Bureau of Laboratories is a CDC's designated "Advanced Reference Laboratory" and has been ready with a validated Ebola test (RT-rtPCR) for a few months. We are talking with hospital laboratories and responding to questions to make sure the laboratory community has accurate, up to date information. We are urging laboratory facilities across the state to continue to assess their testing risks and readiness to respond to patients with potential Ebola virus infection, especially as guidance from the CDC is updated.

Increasingly, questions have been asked about Point of Care (POC) testing of potential Ebola patients, especially concerning a test called BioThreat E, marketed by BioFire LLC, which received an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) recently. After a brief literature search and looking at the FDA documents, we are concerned about some of the published performance data. The EUA documents clearly state that results obtained with the assay should not be used for patient management decisions – a directive that has been strongly reiterated in recent discussions with the FDA. Therefore any facility using it must wait for results from their Public Health Laboratory before proceeding. This means that the test is generally used for data collection and the only way to generate more data of the type needed (detection of new cases in early stages of disease) is by laboratories using it on samples from patients when they present and comparing the data with that from the CDC Laboratory Response Network (LRN)-deployed assay. Association of Public Health ►

Laboratories (APHL) member labs have requested the FDA to facilitate the establishment of a central data bank to compile all such test data in the US and they are working on doing that. The BioFire instrument costs $50,000, validation samples are not available to validate the assay, proficiency samples are not available, positive controls are not available from the company and having a greater number of amplification cycles does not necessarily correlate to an increase in sensitivity. So deployment will be difficult if not impossible and will be valuable only for data generation and not for clinical diagnosis.

As reported by one state lab director, according to the package inserts, the Limit Of Detection (LOD) of the BioFire assay is 600,000 PFU/ml, while that for the LRN-deployed assay is 5,000 PFU/ml. So the likelihood of the BioFire assay detecting infections earlier is highly unlikely and at this point the sensitivity of the assay is a serious concern. Also, according to BioFire, there are very limited supplies of the Biothreat-E test in the US. Therefore the supply issue for lab testing remains a concern.

Lastly, it was pointed out that LRN has not given an "approval" for this test, but ultimately it is not the LRN that has to "give their blessing" to using the BioFire assay. We must point out that there is a clear directive from the FDA (in all documents) that results from the BioFire test must not be used for patient management decisions.

For More About Ebola, check out the American Public Health Association's Ebola Fact Sheet:

http://www.getreadyforflu.org/EbolaFacts.htm

Electronic Test Ordering and Resulting via HL7 Coming to BOL

The MDCH Bureau of Laboratories (BOL) has begun working on incoming and outgoing electronic HL7 messaging for test orders and results for both Newborn Screening and other testing performed at the State Public Health Laboratory. As the health care community moves to an electronic and interoperable environment, the health care community will be able to send test orders and receive test results electronically from the BOL in near real-time fashion. The receipt of orders and results in near real-time is expected to improve patient health and reduce health care costs through early detection and intervention. This development of an electronic message that can transmit an initial order and test results to the ordering provider will significantly reduce the burden on providers and reduce the risk for transcription errors by both parties.

Once implemented, providers will be able to send test orders to the BOL directly from their Electronic Health Records (EHRs). The BOL will send an electronic acknowledgement of the specimen arrival at the BOL to the ordering provider EHR. When testing is completed, will send the result message electronically to the same ordering provider EHR. We will also have the capability to send the result message to multiple "carbon copy" providers upon request.

Benefits of HL7 electronic messaging include:

- Decreased time for test results to be returned to the ordering provider
- Eliminate the need for submitting agencies to hand-write test request forms
- Eliminate the need for submitting agencies to file hard copy results in patient files
- Reduce the risk for transcription error by the submitting agencies in hand writing test requests
- Reduce the risk for transcription error by the BOL when reading hand written test requests
- Reduce the risk of filing errors when placing hard copy test results in patient files
- Reduce the time between result delivery and result availability to the ordering provider.

We expect to have HL7 electronic messaging available to our submitting agencies in the third or fourth quarter of 2015. If you are interested in HL7 messaging with the BOL, we expect to have our Implementation Guide available after the first of the year. Please send HL7 questions to mdchlab@michigan.gov

Note: Our ETOR option for sending in test requests and receiving test results will still be available after HL7 implementation for agencies who wish to continue using this method.

Interim Analytical Chemistry Section Manager– Matthew Geiger

First, on a sad note, we regret to inform you that Dr. Bonnie Taffe, Ph.D., manager for Analytical Chemistry section and interim Director for Division of Chemistry & Toxicology, has resigned her position. Her last day at the bureau was October 10, 2014. Dr. Taffe moved to Jacksonville, Florida to take a new position as the manager of the Newborn Screening Laboratory at the Florida State Health Department . We wish her the very best in her new endeavor.

We are pleased to announce that effective October 13, 2014, Mr. Matthew Geiger, MS, has agreed to serve as Interim Section Manager of the Analytical Chemistry Section. Mr. Geiger will bring a wealth of knowledge to our Analytical Chemistry section, thanks to his experience as Unit Manager in our Fish Monitoring unit. This interim transition is a wonderful opportunity for Mr. Geiger and the Bureau of Laboratories as a whole, to continue to work collaboratively to ensure that we are continually providing the best quality of care for our public health partners and Michigan residents.

Please welcome Mr. Geiger in his new interim position. Please feel free to contact Mr. Geiger regarding any issues related to the Analytical Chemistry Section. His email address is GeigerM@michigan.gov.

Staff Departure– Colin Johnson

Colin Johnson, laboratory scientist in Analytical Chemistry Section, has accepted a new position outside the Bureau of Laboratories (BOL). Colin worked for the BOL for four years; he was an Association of Public Health Laboratories (APHL) Fellow for two years before he was hired as a laboratory scientist through the Michigan Public Health Institute. As a fellow, Colin helped develop an analytical method for the analysis of ploybrominated diphenyl ethers (PBDEs) in human serum by gas chromatography–mass spectrometry (GC-MS). As a laboratory scientist, he worked with human serum for the analysis of polychlorinated biphenyl (PCBs) and chlorinated pesticides by gas chromatography- electron capture detector (GC-ECD). We wish Colin the best with his new position at XG Sciences where he will perform testing on Graphene Nanoplatelets.

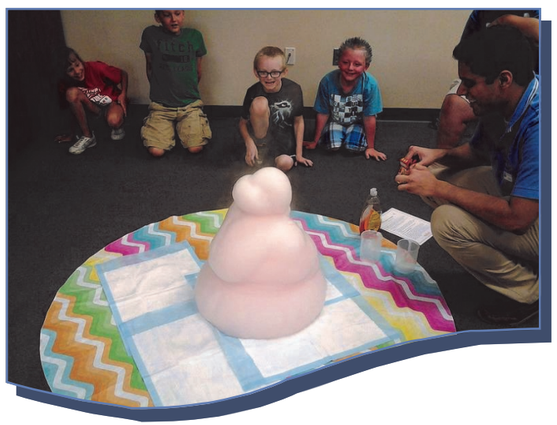
Explore Lab Science Internship Program

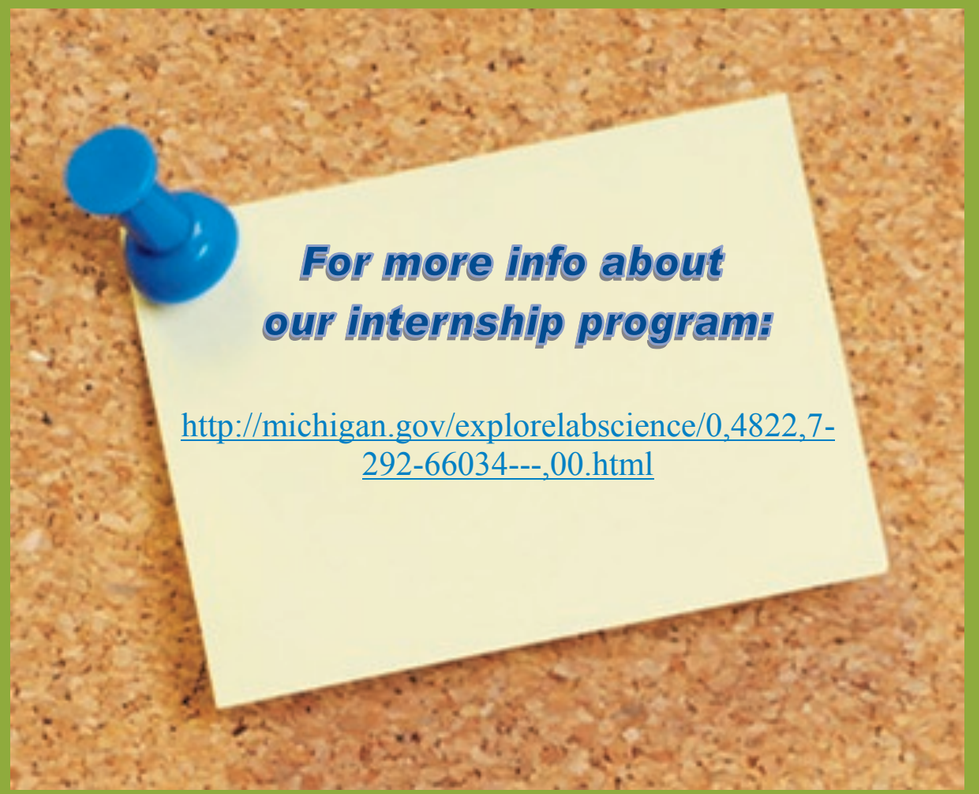
What is the Explore Lab Science Program?

The overall goal of the program is to address workforce shortages within the laboratory science field by introducing students to the profession at an early age. This is accomplished by offering demonstration days (Demo Days) at local schools where students participate in hands-on experiments while learning about careers in laboratory science.

The Bureau of Laboratories hosts about seven college interns per semester to help with our Explore Lab Science Program. College students improve their presentation and leadership skills while learning about public health laboratory testing/ programs.

College students can apply for our Community Health Lab Outreach internship by going to http://agency.governmentjobs.com/michigan/default.cfm.





LabLink is published quarterly by the Michigan Department of Community Health, Bureau of Laboratories, to provide laboratory information to Michigan health professionals and public health community.